REMARKS

Reconsideration of this application is respectfully requested. Claims 25-32 are pending.

Claims 31-32 stand rejected under 35 U.S.C. § 112, first paragraph, as containing new matter; and claims 25-32 stand rejected under § 112, first paragraph, as not being enabled. Each of these rejections is addressed below.

New Matter Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 31-32 stand rejected as containing new matter. The Office contends that the limitation "human cell lines" is not supported by the specification. Applicants respectfully traverse.

Support for the objected to limitations can be found, for instance, at page 9, first paragraph, which describes human peripheral blood mononuclear cells. Withdrawal of the rejection is respectfully requested.

Enablement Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 25-32 stand rejected as not being enabled. The Office contends that while the claims are enabled for *in vitro* activation of immune system cells against HIV, the claims are not enabled for *in vivo* activation. Applicants respectfully traverse the rejection.

The law on enablement, as clearly set forth by the Federal Circuit's predecessor court in In re Marzocchi, requires the Patent Office to provide specific reasons for a §112 rejection:

> As a matter of patent office practice...a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of §112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.
>
> ...
>
> It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

In re Marzocchi, 439 F.2d 220, 223-224 (C.C.P.A. 1971) (emphasis in the original). Furthermore, the evidence or reasoning supplied by the Examiner must be particularized and definite, not broad and general:

> [W]e do not consider that a broad allegation that the application disclosure is speculative, coupled with a recitation of various difficulties which might be encountered in attempting to put it into practice, and a further assertion that there might still be other difficulties which would not be foreseen, constitutes a sufficiently definite statement of a basis for rejection.

In re Chilowsky, 229 F.2d 457, 462 (C.C.P.A. 1956).

The Office has focused its enablement rejection on the functional language contained in claim 25: "composition for *activation of immune system cells against HIV....*" It is

respectfully submitted, however, that the present claims are not directed to a method of treatment, but are rather directed to pharmaceutical compositions. The inquiry, therefore, is whether the specification enables the claimed compositions.

The specification contains a description of the manner and process of making the claimed invention. The claims are directed to a pharmaceutical composition comprising HIV infected cells that have been treated with hyaluronidase. See claim 1. The specification describes the formation of pharmaceutical compositions. See for instance page 5, 2nd and 3rd Full Paragraphs. The specification also provides a detailed description of how to treat HIV infected cells with hyaluronidase, of which the claimed compositions are comprised. See for instance, page 12, Study 2, and page 14, Study 4. Clearly, therefore, the specification teaches how to make the claimed composition.

The specification also discloses how to use the claimed compositions. For instance, techniques of administration and dosage regimens are described at page 5, last paragraph, to page 6, third full paragraph. Since the specification contains a teaching of the manner and process of making and using the claimed compositions, the enablement requirements of § 112, first paragraph, are met. Withdrawal of the § 112 rejection of claims 25-32 is therefore respectfully requested.

As discussed above, the Office's has focused the enablement analysis on the functional language in the claims, rather than on whether the compositions that are actually claimed are enabled. Notwithstanding, Applicants respectfully submit that the Office has not met its burden of supporting its position with acceptable evidence or reasoning.

The evidence cited by the Office does support the enablement rejection. The Office cites Fresheny (Culture of Animal Cells, a Manual of Basic Technique, Alan R. Liss, Inc., 1983, page 4) as indicating that there are many differences between *in vitro* cultured cells and their *in vivo* counterparts. However, Fresheny's observations are general in nature, and are not specific to Applicant's assays. In addition, despite the observed differences between cell environments, Fresheny still directs that "it must be emphasized that many specialized functions are expressed in culture and as long as the limits of the model are appreciated, it can become a very valuable tool." Fresheny, therefore, does not cast doubt on Applicants' invention.

Indeed, Fresheny is not reliable evidence. Fresheny was published in 1983. Fresheny therefore predates Applicants' filing date by about 19 years! The state of the art in 1983 cannot be considered to be indicative of the state of the art in

2002, especially in a rapidly progressing field such as biology. Fresheny, therefore, cannot be considered reliable evidence.

Applicants wish to draw the Office's attention to the factual situation in Burroughs Wellcome Co. v. Barr Laboratories, Inc., 40 F.3d 1223 (Fed. Cir. 1994). Burroughs Wellcome involved a series of patents covering various preparations and methods of using azidothymidine (AZT) in the treatment of persons infected with HIV. Id. at 1224. Burroughs Wellcome screened the AZT compounds, claimed in its patents, for antiretroviral activity using two murine (mouse) retroviruses. Id. at 1225. The alleged infringers argued that conception of the Burrough's Wellcome's claimed invention did not occur until the operability of the invention had been confirmed using an NIH assay which utilized a line of T-cell clones based on the ATH8 cell line. Id. at 1227. The court did not agree with the alleged infringers, ruling instead in favor of the patentees. Id. at 1228.

As noted by the court, enablement and conception are distinct issues, and one need not necessarily meet the enablement standard to prove conception. Id. at 1231. Nevertheless, the court concluded "the enabling disclosure does suffice in this case to confirm that the inventors had concluded the mental part of the invention process [conception of the invention]...." Id. The court, therefore, implicitly believed

that the inventors' murine assays were sufficient for an enabling disclosure.

Applicants' studies utilize human cell lines and HIV, and not a murine virus, as in the Burroughs Wellcome Co. case. Applicants' submit that if the Federal Circuit considers a murine assay to sufficiently enable an HIV drug, then Applicants' assays, which use human cell lines and the HIV virus, are also enabling.

Finally, Applicants' respectfully request the Office to note that Applicants have tested and compared their compositions to AZT in numerous studies, and demonstrated that their compositions surpassed AZT at inhibiting viral proliferation and dissemination in human cell lines. See specification, page 10, Study 1.

For at least the reasons discussed above, the claims are fully enabled by the specification. Accordingly, withdrawal of the § 112 rejection is respectfully requested.

Allowance of the claims and passage of the case to issue are respectfully solicited. Should the Examiner believe a discussion of this matter would be helpful, the Examiner is invited to telephone the undersigned at (312) 913-0001.

Respectfully submitted,

McDonnell Boehnen
Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
Telephone: (312) 913-0001

Date: September 13, 2004 By: Raafat Shaltout
Raafat Shaltout
Reg. No. 45,092